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Comments from Academic, Scientists, and Clinicians on the Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances

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These comments are submitted on behalf of the undersigned academic, scientists, and clinicians. We declare collectively that we have no direct or indirect financial or fiduciary interest in the manufacture or sale of any chemical under consideration of these risk evaluations.

We appreciate the opportunity to provide written comments on the Agency's efforts to establish the scope of risk evaluations under development for the first ten chemicals substances designated on December 19, 2016 for risk evaluations pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety of the 21st Century Act. This opportunity to provide information on the conditions of use for these first ten chemical substances (i.e., the circumstances under which a chemical substance is intended known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of) will be an important consideration in the development of scoping documents for the TSCA risk evaluations of these ten chemical substances. EPA held a public meeting on February 14, 2017 in Washington D.C. and several of the undersigned submitted oral comments at that time. We appreciate this subsequent follow-up opportunity to submit further comments and to respond to information shared by EPA and other public commenters during this meeting.

We strongly support EPA in its efforts to improve hazard evaluation of chemicals through the Frank R. Lautenberg Amendments to TSCA to make them timely and health protective. Such improvements are urgently needed and long overdue as previous efforts to regulate environmental chemicals through TSCA have been minimally effective in preventing exposures before they occur in the population. We hope the new Lautenberg Amendments to TSCA affords EPA a critical opportunity to take action to reduce exposures to chemicals that are recognized as potential hazards following their risk evaluation. We recommend the Agency continue to fulfill these statutory mandates in a timely manner while also supporting the Agency's overall duty to protect public health and prevent harmful exposures to environmental chemicals.

In fulfillment of these mandates, we recommend EPA should:

1. **Incorporate a broad consideration of chemical use profiles that captures current uses in addition to reasonably foreseen applications that consider the full cradle-to-grave chemical lifecycle;**

2. **Ensure that the chemical evaluations are designed to be fully protective of public health, particularly the health of vulnerable and susceptible populations, and adequately capture real-world scenarios by considering aggregate exposures;**

3. **Not solely rely on the use of product labels (such as those specifying use of Personal Protection Equipment (PPE)) to guarantee health protection of occupational workers and consumers, as these are inadequate to fully protect public health;**

4. **Not assume that absence of data means that there is no hazard or risk: these data voids should be identified during scoping and problem formulation activities, and efforts to obtain or generate the required data should be pursued immediately.**

5. **Encourage and actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate.**

Collectively, as academics, scientists, and clinicians, our research goals involve creating a healthier environment for human reproduction and development. We work towards this mission by advancing scientific inquiry, clinical care, health policies and regulations that prevent exposures to harmful chemicals in our environment, particularly during critical time periods of life stages, such as pregnancy or during child development, that can have acute or long-term impacts on individual health and which may even persist through several generations.

The Agency's efforts to establish the scope of risk evaluations under development for the first ten chemicals substances is an extremely critical opportunity for EPA to prevent potential harmful exposures of chemicals to people in their homes, workplaces, and outdoor environments. We have seen time and time again examples of chemicals used in household and workplace products and goods whereby thousands and millions of people are exposed, only to ultimately find that these chemicals are harmful to human development, reproduction, and general public health. The process for removing these chemicals from commerce is no simple feat, as we still see harmful chemicals like lead, asbestos, and flame retardant chemicals still contained within products by which we are exposed to this very day and may continue to be for many decades. Therefore, it is of utmost importance to design appropriate risk evaluations that will enable the Agency to identify potential hazards and act accordingly in a timely fashion to ensure public health protection from these exposures.

Evaluating the conditions of use for each chemical will be a critical piece of these evaluations, as this establishes the exposure profiles and identifies subpopulations that are exposed at high levels, exposed over long periods of time, or those considered vulnerable or susceptible. In particular for these first ten chemicals slated for evaluation, virtually all are commonly used in easily obtained consumer products, manufactured at high volumes within the United States or internationally imported from other countries, and reported to have high volume of release to the environment, leading to potential contamination in air, water, soil and food. As such, it is critical that EPA identify accurate information regarding how and in what volumes these chemicals are manufactured, processed, distributed, used, disposed of, and recycled in the real world so as to understand true population exposures and subsequently protect from potentially harmful health effects.

We support the Agency in its efforts to satisfy its statutory mandate through the Frank R. Lautenberg Amendments to the Toxic Substances Control Act. We strongly recommend the Agency continue to fulfill these statutory mandates in a timely manner while also supporting its overall duty to protect public health and prevent harmful exposures to environmental chemicals. In support of this, we offer the following specific recommendations:

1. Incorporate a broad consideration of chemical use profiles that captures current uses in addition to reasonably foreseen applications that consider the full cradle-to-grave chemical lifecycle.

We strongly agree with the EPA that their risk evaluation "…must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance." In order to accomplish this, EPA must consider a broad range of potential uses for each chemical, potentially beyond what is stated in the Pre-Manufacture Notice (PMN) provided by the manufacturer or reported by Chemical Data Reporting (CDR) because, among other reasons, future uses of the chemical might change. This will grant EPA the necessary flexibility to anticipate potential changes in the chemical's use in the future and apply judicious assumptions to protect the public's health from exposures deviating from the initial use intent.

In considering "reasonably foreseen uses," EPA must consider the cradle-to-grave lifecycle of the chemical. Exposures and contamination from the manufacture or use of chemicals in products is but a small portion of the overall picture—the entire lifecycle of research and development and testing where there may be occupational exposures or environmental releases, to manufacturing, transportation, usage and disposal. This full lifecycle must be considered in order to evaluate the totality of potential exposures to workers and the public as well as potential releases to soil, water, air, or food. These must all be carefully considered for incorporation into the chemical risk evaluations.

EPA should also closely examine any uses of the first 10 chemicals as intermediates in the synthesis of other chemicals. These commercial uses are extremely relevant, as they pose exposure risks to workers that may entail higher exposure volumes or concentrations over an extended period of time that could pose greater potential risks for workers. Additionally, occupational exposure levels can vary widely based on the manufacturing process employed or specific details of the environmental conditions during processing. Therefore, this important opportunity for exposure warrants careful consideration and incorporation into the use profile of the chemical.

Many of these chemicals can be readily found in consumer products easily purchased off the Internet or in stores. At the February 14th meeting, the Environmental Defense Fund presented a compilation list of products readily purchased from the internet that contain at least one of the first ten Work Plan Chemicals being evaluated under the Lautenberg Amendments. We also heard about how many of these chemicals are used in products that would be readily used by children—for instance, HBCD used in mattresses, furniture, car seats, nursing pillows and beanbag chairs. Environmental monitoring studies further support the potential for exposures, for example studies that have found HBCD in household and daycare dust at very high levels.[1,2,3] Risk evaluations for chemicals contained in products that are easily accessible, routinely used, or known to be detected at high levels in homes should subsequently include a broad range of potential uses and exposures resulting from the use of products for purposes beyond those indicated or intended by the product manufacturer to adequately capture the potential exposures that may occur in general or susceptible populations.

EPA should use the highest quality evidence and information to support their findings in a way that supports timely decision-making. To accomplish this, EPA should leverage existing data sources by seeking knowledge about specific chemicals or analogues that have already been documented in risk or hazard evaluations completed by EPA, other government agencies (such as the National Toxicology Program or the California Environmental Protection Agency), or other authoritative body (International Agency for Research on Cancer) to extrapolate findings to the chemical under review when appropriate. These assessments provide useful data and information on use profiles of chemicals as well as evidence summaries and integration of existing data and can provide a critical immediate source of data on recognized hazards. Other federal agencies such as the Occupational Safety and Health Agency (OSHA) and the National Institute of Occupational Health Safety (NIOSH) may have additional information on the uses of these chemicals in the workplace, including medical surveillance data that may be of use. Lastly, EPA should require data on uses, exposures, and releases from chemical manufacturers, processors, distributors, and recyclers and also make concerted efforts to confirm the accuracy or reported data and information.

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[1] Abdallah, M.A., Harrad, S., Ibarra, C., Diamond, M., Melymuk, L., Robson, M., Covaci, A. 2007. Hexabromocyclododecanes in indoor dust from Canada, the United Kingdom, and the United States. Environmental Science & Technology. 42(2):459-64

[2] Covaci, A., Gerecke, A.C., Law, R.J., Voorspoels, S., Kohler, M., Heeb, N.V., Leslie, H., Allchin, C.R., and DeBoer, J. 2006. Hexabromocyclododecanes (HBCDs) in the Environment and Humans: A Review. Environmental Science & Technology. 40:679-3688

[3] Harrad, S., Goosey, E., Desborough, J., Abdallah, M.A., Roosens, L., Covaci, A. 2010. Dust from UK primary school classrooms and daycare centers: the significance of dust as a pathway of exposure of young UK children to brominated flame retardants and polychlorinated biphenyls. Environmental Science & Technology. 44(11):4198-202

2. **Ensure that the chemical evaluations are designed to be fully protective of public health, particularly the health of vulnerable and susceptible populations, and adequately capture real-world scenarios by considering aggregate exposures.**

EPA is now mandated by the Lautenberg Amendments to specifically consider and protect against risks for susceptible or vulnerable populations. We are fully supportive of this new provision, and encourage EPA to consider for every chemical review: (1) occupational exposures that are often at much higher exposure levels than the general public, both acutely and chronically, and can be concurrent with other chemical exposures at the workplace;[4] (2) fence-line communities who also face multiple exposures to multiple chemicals and suffer from many chronic health conditions and health inequalities; (3) sensitive time periods during life, such as pregnancy and during childhood; (4) tribal communities where cultural and lifestyle considerations may result in very different exposure profiles and where there are often disproportionate adverse health outcomes; and (5) general variability in human responses.

When evaluating risks for each chemical, EPA should consider and include a broad range of uses and exposure pathways that reasonably captures the potential exposures faced by these particular populations. Key exposure pathways must be considered, including dermal and inhalation, diet and drinking water, exposures to communities near facilities where chemicals are manufactured, processed, or disposed of and recycled, and exposures to the workers in manufacturing, processing, disposal and recycling facilities, as well as key toxicity endpoints such as developmental, reproductive and neurological toxicity, which are hazards of high concern for pregnant women and children.

Several times over the course of the February 14th public meeting, speakers affiliated with the chemical industry made claims that their chemicals are produced only in "closed systems" and thus the potential for human exposure should be assumed as non-existent or minimal. We strongly encourage EPA to develop rigorous criteria to define what scenarios constitute a true "closed system" with zero human exposures, and require an evaluation of these criteria to substantiate industry claims that expected exposures are minimal. Accepting the assumption that exposures are zero based on simply the claim that it is a "closed system" without a rigorous evaluation of whether this is truly the case would be inappropriate and a failure to ensuring public health protection.

Furthermore, aggregate exposures should also be considered, especially for communities that have legacy contamination or those that concurrently face a high burden of multiple chemical exposures in their daily lives. This is supported by the EPA's Environmental Justice view, and these principles should carry over into the evaluation of risk for the chemicals under consideration. In general, the scope of this process must be broad, inclusive, and precautionary in nature. Furthermore, several of the first ten chemicals are contained within products outside of the scope of TSCA (such as cosmetics) in high volumes—these existing exposures should be considered as non-zero background exposures of the population from which other exposures additionally contribute in an aggregate manner. This is extremely important to consider since cosmetics and personal care products represent some of the highest exposures to people, since they are applying them directly to their bodies often multiple times per day every day.

Occupational workers exposed during the manufacture, processing, disposal, etc. of these chemicals should always be considered separately as a susceptible population. Furthermore, the consideration of exposed workers should **always** include the potential for pregnant women and consider both women and men of childbearing age as a vulnerable population when assessing the risk. Workers can be exposed to

[4] Hines CJ, Jackson MV, Deddens JA, Clark JC, Ye XY, Christianson AL, Meadows JW, Calafat AM. *Urinary Bisphenol A (BPA) Concentrations among Workers in Industries that Manufacture and Use BPA in the USA.* Annals of Work Exposures and Health. 2017. DOI: https://doi.org/10.1093/annweh/wxw021

high levels of these chemicals and/or over a relatively long duration; exposures to men and women of childbearing age and pregnant women can pose potential serious consequences for the health outcomes of the developing fetus and lasting consequences for brain development, cognition and behavior in their children.

3. Not solely rely on the use of product labels (such as those specifying use of Personal Protection Equipment (PPE)) to guarantee health protection of occupational workers and consumers, as these are inadequate to fully protect public health.

Reliance on product labels such as those specifying the use of PPE is **not** sufficient. The EPA Office of Chemical Safety and Pollution Prevention (OCSPP) released a report in March 2016, "The Effectiveness of Labeling on Hazardous Chemicals and Other Products,"[5] which found that consumers and professionals do not consistently pay attention to labels and that they do not understand label information.

In particular, most studies found that the primary influential factor in whether or not consumers paid attention to labels for household chemical products was the type of product and user familiarity with the product. Increased user familiarity decrease the level of attention a user paid to cautionary statements on labels or use instructions. Therefore, the people who are using these chemicals most often are likely the ones who pay the least attention to the label or instructions. When experienced users read labels they may not understand information that contradicts what they previously knew from past experiences. For example, if they have been taught a way to handle the chemical through their experience they are less likely to alter these behaviors, even if instructions are written on the label. Furthermore, if risk information changes for the same product, users are less likely to read, process, or abide by the new directions because they rely more heavily on their past experiences using the product. Therefore, the assumption that the use of PPE is guaranteed simply because it is specified on the product label is not appropriate.

The primary factors that influences whether a user understands the information on the label are the users' literacy and numeracy, which frequently correlate with the users' education and income. Therefore, people with less education, lower income, and less advanced literary skills will be at the highest risk for misusing products. These individuals also disproportionately bear the burden of exposures to multiple environmental hazards and the resulting health impacts; therefore placing further burden on this already stressed susceptible subpopulation.

When evaluating risk, EPA needs to take into consideration **all** potential and feasible routes of exposure and **should not** exclude exposure routes because it is assumed there are exposure controls in place. These controls are not guaranteed and may change in the future, so to assume zero exposure via these routes would be inappropriate and a failure to adequately ensure public health protection.

4. Not assume that absence of data means that there is no hazard or risk: these data voids should be identified during scoping and problem formulation activities, and efforts to obtain or generate the required data should be pursued immediately.

EPA must consistently make clear that **absence of data does not mean there is no hazard or risk.** The only appropriate interpretation of a data gap is that the hazards and risks are "unknown." These data voids should be identified during the scoping and problem formulation activities and efforts to obtain or

[5] US Environmental Protection Agency (EPA). 2016. "The Effectiveness of Labeling on Hazardous Chemicals and Other Products." Office of Chemical Safety and Pollution Prevention. RIN 2079-AK07.

generate the required data should be immediately undertaken. EPA should explicitly identify critical data gaps and needs in the problem formulation stage and require the development of health and safety information from manufactures and processors through the issuance of test orders. However, it is critical that EPA not wait for the generation of data to conduct risk evaluation for uses where sufficient information exists in order for the process to proceed in a timely manner. It is critical that EPA base its decisions on the best science available while also acting in a timely manner to fulfill its mission to ensure public health protection for all people. In the absence of data, EPA should consider incorporating science-based defaults as recommended by the National Academy of Science (NAS)[6,7] to incorporate factors that reflect the range of variability and susceptibility in the population to ensure risks are not underestimated.

5. **Encourage and actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate.**

At the February 14 meeting, EPA highlighted their active role in seeking participation from various stakeholders such as environmental groups, public health groups, other federal agencies, states, trade associations, union representatives, and academics. However, noticeably missing from this list were members from the public such as fence-line communities living near industries, processing plants, recycling facilities, or Superfund sites; other concerned members from the public, such as susceptible or vulnerable subpopulations; occupational workers; or tribal communities. We strongly encourage EPA to actively seek the participation and input of these groups and incorporate their concerns in these evaluations, as these members of the public will be the ones handling or using these chemicals and likely impacted by their adverse health impacts.

We are very appreciative for the opportunity to provide public input and we are looking forward to continuing to participate in such opportunities in the near future. Please do not hesitate to contact us with any questions regarding these comments.

Respectfully,

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[6] National Research Council. *Science and Decisions: Advancing Risk Assessment.* Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, Board on Environmental Studies and Toxicology, and Division on Earth and Life Studies. 2009. Washington, D.C. National Academies Press.
[7] National Research Council. *Phthalates and Cumulative Risk Assessment: the Task Ahead.* 2008. Washington, D.C. National Academies Press.

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